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14. ABSTRACT

This study is a follow up to two projects, funded by the Office of Naval Research, which demonstrated that Virtual Reality (VR) Exposure Therapy was safe for the treatment of combat PTSD Disorder, and that it worked better than treatment as usual. In this study, we are attempting to discover if the Virtual Reality is actually the active component of the treatment. Participants with PTSD are randomized to receive the same treatment that was successful in the previous projects, or the same treatment in which a simple, still computer image replaces the VR. At the last annual review, our findings were indicating that VR treatment and the control condition resulted in similar improvements, but that improvements in the VR condition persisted whereas those in the control condition did not. In the last year, we have continued to recruit, assess, and treat individuals with combat related PTSD. Results with our larger sample size continue to demonstrate similar findings as last year's analysis. We have presented these findings at the American Psychiatric Association and will be presenting them at the International Society for Traumatic Stress Studies meeting. Sample size has not yet reached our original target, and we do not yet have enough data to examine particular predictors of treatment success. We hope to reach these goals in our final year of study.

15. SUBJECT TERMS

Post-Traumatic Stress Disorder, Anxiety, Depression, Virtual Reality, Psychotherapy, Exposure Therapy

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INTRODUCTION: This study is intended to determine if the Virtual Reality (VR) simulator used in Virtual Reality Exposure Therapy (VRET) is the active component when using the technique to treat combat-related PTSD. It is a multi-site, randomized, single blind comparison of VRET versus a control condition that uses all the same components of therapy, except that a single, still computer image is used to focus a subject's attention rather than having him/her use a full, VR simulator. The VRET is conducted in the same fashion as has been previously used to treat combat PTSD. Subjects receive therapy for up to twice a week therapy for ten weeks. Subjects are assessed by independent, blinded raters before and after treatment, and three months later to determine long-term follow up. Success is determined by showing improvements on the Clinician Administered PTSD Scale (CAPS). The study was designed to complete treatment of 80 subjects (40 active and 40 controls) over the course of 4 years. A fifty percent dropout rate was anticipated. The study was to be completed at two military facilities, Naval Medical Center San Diego (NMCSD), and Marine Corps Base Camp Pendleton (CP). We were attempting to add a third site, at Naval Hospital Yokosuka, Japan, but we were unable to do so. We have, however, expanded the number of providers and sub-clinics within NMCSD and CP that provide VR therapy. The first stage of the project was to recruit and train research therapists, and research assistants, to obtain IRB approval to conduct the study, and to set up measures to ensure and monitor protocol adherence and progress. This includes both weekly research meetings, and annual safety and efficacy review in which data is compiled each year to ensure that subjects in either the active or the control condition are not receiving care that is anything less than ideal. Because of funding cuts to the original budget, the study is dependent on including volunteer research therapists and research assistants who work on the project without cost to the grant. The second stage of the project was to maintain recruitment, treatment, and data gathering. The third stage is to track long term outcomes, and to analyze and present findings.

BODY:

The study has recruited and trained research personnel, obtained IRB approval, set up review and safety procedures, and been steadily recruiting, assessing, and treating research subjects. We have had a flow of volunteer therapists in and out of the program over the last year. Unfortunately, this included the departure of our volunteer therapist, and potential site PI, at Yokosuka. However, we have had three new volunteer therapists join, and one of our previous therapists who had been on extended hiatus recently return to us. This includes a therapist at NMCSD's residential PTSD program. Once she has completed her training case, this should ensure a steady flow of participants via that program.

Currently, we have seven therapists actively treating patients, and six simulators where treatment can be conducted. With this number, we are currently able to treat up to eleven patients at a time. We will be temporarily losing one of our therapists to maternity leave, but also gaining the volunteer services of a therapist in a residential PTSD program. She anticipates treating four patients at a time on a consistent basis. We need to maintain four subjects in treatment at all times to maintain project goals. As might be expected from working with volunteer, active duty therapists, there has been some personnel turnover as therapists move between commands and compete with other obligations. Therapists

must have prior experience in traditional exposure therapy, complete IRB research requirements, and complete a supervised "training case" in VRET before we would include data from subjects treated by that provider. All research therapists also participate in a weekly supervision and monitoring meeting (in person or by video conference) in which protocol adherence is maintained. We have conducted several training seminars for military therapists, and at various times, had twelve therapists formally credentialed for the project. We anticipate that one of our paid therapists will be going on maternity leave soon, but the increase in volunteer therapists should make up for her temporary absence. So far, 120 subjects have given informed consent to be assessed for the study. Twenty two of these did not meet study criteria and were excluded. Eight subjects were treated by a first-time therapist, and therefore were considered "training cases", with data excluded from analysis. Twenty four subjects elected not to enter treatment (dropped out prior to randomization). Eight participants dropped from the study after enrollment. One of these four was due to an adverse event (becoming suicidal during treatment). The others electively left the program. Fifty-four subjects completed treatment and a post-treatment assessment. Four subjects are currently in treatment. Forty two subjects have contributed long-term (3 month +) follow up data**.** Recruitment is ongoing.

We completed our annual, safety and efficacy review in preparation for the annual IRB review. No statistically significant differences are being observed at this point between those in the Active (virtual reality) and Control conditions. Both groups of subjects experienced statistically and clinically significant improvements over the course of treatment. At three month follow up the improvements seen in the control condition have reverted. Although the scores are numerically lower than there were pre-treatment, the measured improvements in PTSD are no longer statistically significant. This contrasts with the active-VR condition in which the PTSD scores are numerically better at 3 months even than they were post-treatment and this score difference continues to be statistically significant. Of note, however, although the PTSD scores for the VR group are numerically lower than the controls at the 3 month follow up, this difference between groups is not yet statistically significant.

Weekly supervision meetings for protocol adherence and safety monitoring are ongoing according to plan.

There have been two presentations and abstracts completed from this project within the last year, both presented at the American Psychiatric Association Annual Meeting in Philadelphia, PA in May of 2012. One of these was part of a larger panel discussion on new technology for PTSD. A third abstract has been accepted for presentation in November of 2012 at the International Society for Traumatic Stress Studies in Los Angeles, CA. An additional abstract is currently in preparation for the American Psychological Association meeting next year.

Safety and IRB review has been completed for the year, and we intend to continue on with our current methods. We have not yet received the final approval letter from the annual IRB review, but anticipate this at any point.

Only one item from the statement of work is relevant to the current study period: Task 2: Month 7 to month 42: Recruit and enroll approximately 8 patients per treatment period, with the expectation that 4 of these will enter VRET or CET treatment phases, and

be eligible for intention to treat analysis.

We have consented 120 of our target 160 subjects that we anticipated enrolling for the entire study (75% of target). We were hoping to complete treatment on 80 participants, and so far 66 subjects have completed or are in treatment (82.5% of target). The need to depend on volunteer therapists, and train them, has meant that we have four times the anticipated number of training cases as initially anticipated. This means that that only 58 of the 66 participants will be eligible for final analysis (72.5 of target)%. At present rates, we are on target to continue to recruit and treat patients as outlined by Task 2. At this rate we would treat another 20 patients in the next year, and reach 95% of our original target by the end of the project. We hope that with the addition of our new therapists, we will be able to exceed this rate, and reach 100% of our target by next year.

KEY RESEARCH ACCOMPLISHMENTS:

- Key personnel and procedures in place to conduct and test Virtual Reality Exposure Therapy versus the control condition
- Annual safety and efficacy review was conducted, which showed that subjects are improving in both treatments. So far, there are no statistically significant differences between groups. However, the active VR group is showing significant differences in PTSD symptoms 3 months out from treatment, whereas the control group is not.
- All elements in place to continue to treat subjects and gather data for the following year.

REPORTABLE OUTCOMES:

We presented preliminary findings of the study at the 2012 American Psychiatric Association meeting in Philadelphia, PA. News of this was reported by NewScientist Magazine http://www.newscientist.com/article/dn21822-virtual-reality-provides-relief-from-soldiers-trauma.html and repeated by other press outlets. We have one other abstract accepted for publication/presentation, and have another abstract in preparation. .
This project continues to be highlighted as part of VIP visits to Naval Medical Center San Diego.

Six Virtual Reality simulators have been established in military mental health clinics. Thirty two therapists from military clinics have been given basic instruction in how to conduct virtual reality therapy, and twelve therapists have completed training to the point that they could function as therapists on the grant. Seven therapists are currently active in this role.

CONCLUSION: Preliminary findings confirm previous reports that VRET is a safe and effective treatment for combat-related PTSD. So far we do not have definitive evidence to say that the virtual reality simulator actually improves outcomes when compared to the same techniques used without benefit of the advanced technology. However, preliminary analysis indicates that gains when using the VR simulator are more likely to persist than those in traditional exposure therapy treatment. We are on track to complete the project in the next year, and report definitive results.

REFERENCES: Not applicable.

APPENDICES: None

SUPPORTING DATA: Not applicable.